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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,294	11/28/2003	Raymond Robert	40128/00801	1169

7590
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EXAMINER

MATTER, KRISTIN CLARETTE

ART UNIT

PAPER NUMBER

3771

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/724,294

Applicant(s)

ROBERT ET AL.

Examiner

KRISTEN C. MATTER

Art Unit

3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/02)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This Action is in response to the amendment filed 3/4/2008. Claims 8 and 36 have been amended and no claims have been added or cancelled. Currently, claims 1-37 are pending in the instant application.

Response to Arguments

Applicant's arguments, filed 3/4/2008, with respect to the Parker reference teaching pumps that are dependent on each other and Federowicz teaching mixed-mode liquid ventilation have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Shaffer et al.

Allowable Subject Matter

The indicated allowability of claims 9-11 and 25-30 is withdrawn in view of the newly discovered reference(s) to Shaffer. Examiner apologizes for any inconvenience this may cause. Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 8, 12-14, 31, 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaffer et al. (US 5,335,650, herein referred to as “Shaffer”) in view of Shaffer et al. (US 6,105,572, herein referred to as “Shaffer ‘572”).

Regarding claims 1 and 14, Shaffer discloses a system and method for applying liquid ventilation comprising supplying oxygenated liquid to the lungs of a patient during inspiration (column 8, lines 50-55) via an inspiration pump (10); withdrawing liquid from the patient's lungs during expiration (column 16, lines 53-60) via an expiration pump (24); and independently controlling the supply and withdrawal of liquid to/from the patient via a ventilator controller (50) having independently controlled inspiration and expiration profiles (column 15, lines 35-55 and column 16, lines 50-65). Shaffer does not specifically mention whether the liquid ventilation is total or mixed-mode. However, Shaffer '572 discloses a similar liquid ventilator with inspiration and expiration pumping systems for performing total liquid ventilation (see column 1, lines 1-10). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have performed total liquid ventilation as taught by Shaffer '572 in the system of Shaffer in order to treat a given condition by eliminating air/fluid interfaces in the lung dependent on a patient's presented condition and a physician's desired treatment regime.

Regarding claims 8 and 36, the breathing profiles taught by Shaffer are linear slopes as seen in Figure 1A (i.e., there are an infinite number of linear slopes on the profile curves).

Regarding claims 12 and 31, Shaffer discloses PFC liquids (column 2, lines 25-30).

Regarding claims 13 and 37, Shaffer discloses modifying the inspiration and expiration profiles (column 15, lines 45-50 and 64-66, column 16, lines 55-60, and column 17, lines 8-10).

Claims 2-7, 9-11, 15, 16, 19, 27-30, and 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaffer and Shaffer '572 as applied to claims 1, 8, 12-14, 31, 36, and 37 above and further in view of Parker (US 5,606,830).

Regarding claims 2 and 15, Shaffer discloses that the liquid is oxygenated but does not specifically mention an oxygenator unit. However, Parker discloses a liquid ventilator with an oxygenator unit (30) that oxygenates the withdrawn liquid from the patient. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the system of Shaffer with an oxygenator unit as taught by Parker because it would have provided a well known and commonly used means for producing the oxygenated liquid supplied to the patient.

Regarding claims 3, 16, and 19, the modified Shaffer system discloses conduits connecting the inspiration and expiration pumps to the patient (see Figure 9; with the addition of an oxygenator as discussed above, an additional conduit would obviously be in place) and valves (12, 25) connected to the controller as discussed above but Shaffer is silent as to the type of pumps involved (i.e., piston). However, absent a critical teaching and/or a showing of unexpected results from using a piston pump, examiner contends that selection of a piston pump (or any other fluid pumping means) in the system of Shaffer is an obvious design consideration to one of ordinary skill in the art in order to produce movement of the liquid to and from a patient. Furthermore, it appears as though the device of Shaffer would perform equally well with a piston pump, which are well known and commonly used in liquid ventilation.

Regarding claims 4-7 and 32-35, the modified Shaffer reference has all of the structural limitations/means needed to transfer the liquid as claimed and to extend or reduce a time of

residence in the oxygenator by controlling the pumps independently. Specifically, Shaffer also discloses correcting inspiration and exhalation times and frequencies and monitoring the oxygenation level of liquid as discussed above. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified a residence time of liquid in the oxygenator unit or to produce the claimed pauses in order to ensure that the liquid is properly oxygenated before delivering it to a patient. Furthermore, it appears as though the method and system of Shaffer would perform equally well with the controller creating the claimed pauses and inspiration/expiration start times.

Regarding claims 9-11 and 27-30, the modified Shaffer reference has all of the structural limitations/means needed, including a buffer reservoir (26) and means for measuring the patient's lung volumes (32, 33) in order to correct lung volumes as needed. Shaffer is silent as to how the sensors determine the volumes. However, absent a critical teaching and/or showing of unexpected results from determining FRC by measuring the level of liquid in the reservoir, examiner contends that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have measured the level of oxygenated liquid in the reservoir to determine/monitor the patient's lung volume parameters because monitoring an amount of liquid that is expired by a patient is a well known and commonly used means for determining a patient's lung volume parameters. Furthermore, it appears as though the modified device of Shaffer would perform equally well by determining the volume of liquid in the reservoir.

Claims 17, 18, and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaffer, Shaffer '572, and Parker as applied to claims 2-7, 9-11, 15, 16, 19, 27-30, and 32-35 above and further in view of Raibel (US 5,770,149).

As to claim 17, Shaffer as modified by Parker lacks the further specific limitations of the oxygenator. However Raibel (in figs. 1-3) teaches an oxygenator comprising: a lower perforated membrane (fig.3, 74) to supply oxygen to the liquid; an inner cylindrical section having an upper (28) end to which the liquid withdrawn from the patient's lungs is supplied; an outer annular section separated from the inner cylindrical section by a cylindrical partition and communicating with the inner cylindrical section through an annular passage between a lower end of the cylindrical partition and the perforated membrane (see fig.3); and an outlet (108) for supplying oxygenated liquid from the annular section, said outlet being positioned at a level that determines the level of liquid in the oxygenator. Therefore, it would have been an obvious design consideration to one of ordinary skill in the art to use any well known oxygenator or to further modify Shaffer to include a perforated membrane, cylindrical and annular sections as taught by Raibel in order to provide a well known and commonly used means for oxygenating the liquid effectively enough to provide it to patient. Furthermore, it appears as though the system of Shaffer would perform equally well with the claimed oxygenator.

As to claim 18, Raibel teaches the oxygenator is formed as a modular unit connectable to other similar oxygenator modular units; the system for applying total liquid ventilation comprises a plurality of said modular oxygenator units connected in series and/or parallel (col.2, lines 51-54).

As to claim 20, Raibel teaches the oxygenator is formed as a modular unit connectable (in parallel series, col.2, lines 51-54) to other similar oxygenator modular units; and each oxygenator modular unit comprises an integrated heating unit (12) for warming the liquid at a predetermined temperature.

As to claim 21, Raibel teaches the oxygenator comprises a lower tubular wall (26); and the heating unit comprises a heating element (12) wound around the lower tubular wall of the oxygenator.

As to claims 22 and 23, Raibel teaches a filter unit (122) being integrated to the oxygenator. However, absent a critical teaching and/or showing of unexpected results from having the filter before the oxygenator, examiner contends that whether the filter is located before the liquid enters the oxygenator or within the oxygenator is an obvious design consideration to one of ordinary skill in the art because both would provide the necessary filtering and the change involves a mere rearrangement of parts that does not patentably distinguish the invention over the prior art. Furthermore, it appears as though the modified device of Shaffer would perform equally well with the filter being located within or before the oxygenator so long as the liquid was being effectively filtered.

Claims 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaffer, Shaffer '572, and Parker as applied to claims 2-7, 9-11, 15, 16, 19, 27-30, and 32-35 above and further in view of Kumar (US 6,983,749). Shaffer as modified by Parker lacks a condenser as claimed. However, Kumar teaches condensers in a liquid ventilating system for recovering liquid (see col.21, lines 53-55). Therefore, it would have been obvious to one of

ordinary skill in the art at the time the invention was made to further modify Shaffer in order to provide condensers for the purpose of recovering liquid as taught by Kumar. The term “condensers” implies that there are more than one condenser. Absent a critical teaching and/or a showing of unexpected results from the location of the condenser, where the condensers are located (i.e., integrated into an oxygenator) is considered an obvious design consideration to one of ordinary skill in the art that involves a mere rearrangement of parts that does not patentably distinguish an invention over the prior art. Furthermore, there is nothing structurally that would prevent the condenser from being integrated to an oxygenator and it appears as though the modified Shaffer device would perform equally well with the condenser being integrated to one oxygenator so long as the liquid was still being recovered.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTEN C. MATTER whose telephone number is (571)272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kristen C. Matter/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771